UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ZYDUS WORLDWIDE DMCC, Plaintiff, v. TEVA API INC., Defendant.	Civil Action No. 19-cv-17086 (JXN) (JRA) **OPINION**

Plaintiff Zydus Worldwide DMCC ("Zydus") filed a Motion for Leave to Supplement Certain Expert Reports ("the Motion"). ECF Nos. 201-02, 209. Defendant Teva API Inc. ("TAPI") opposes the Motion. ECF No. 206. At the heart of this dispute is whether any of the expert reports at issue are incomplete or incorrect in a material respect, such that supplementation should be permitted under Rule 26(e) of the Federal Rules of Civil Procedure. The Court has considered the parties' submissions and reaches a decision without oral argument. *See* Fed. R. Civ. P. 78(b); L. Civ. R. 78.1(b). For the reasons that follow, the Motion is **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND AND PROCEDURAL HISTORY[1]

Zydus filed a complaint on August 22, 2019, claiming that TAPI breached the terms of a Letter of Intent ("LOI"). *See generally* Compl., ECF No. 1. Zydus alleges

[1] The Court assumes the parties' familiarity with the factual and procedural background of this matter given its extensive history. Therefore, the Court includes only the factual and procedural history necessary to decide the Motion.

that it purchased assets related to the sale and manufacture of generic rotigotine transdermal products from TAPI's parent company, Teva Pharmaceutical Industries Ltd. ("Teva"). *Id.* ¶ 1. Zydus claims to have been induced into executing the transaction with Teva because TAPI issued a LOI, under which TAPI agreed to supply Zydus with Form I rotigotine. *See generally* Compl. Form I rotigotine is the active pharmaceutical ingredient required to obtain FDA approval for the products that TEVA sold to Zydus. *See id.* ¶¶ 1-2. TAPI allegedly failed to supply Form I rotigotine to Zydus, thereby depriving Zydus of the opportunity to obtain FDA approval for the generic rotigotine products. *See id.* Through this lawsuit, Zydus seeks to recover from TAPI the extensive losses it allegedly has suffered as a result of TAPI's failure to supply Form I rotigotine. *Id.* ¶ 4. Additionally, Zydus seeks to compel TAPI to supply the Form I rotigotine so that Zydus may finally realize its acquisition. *Id.*

Procedurally, expert discovery ended on October 31, 2022 (ECF No. 140),[2] and the parties engaged in summary judgment briefing between January 27, 2023, and May 12, 2023 (ECF Nos. 149-72). On December 12, 2023, while the motions for summary judgment were pending, the parties informed the Court of a dispute via a joint letter that led to the current Motion: *i.e.*, that Zydus wanted to supplement its expert reports, which TAPI opposed. ECF No. 190. For the sake of efficiency, the Court ordered that Zydus file this Motion after the Court issued its summary judgment decision, as that decision could have mooted or substantially narrowed the

[2] The deadline to serve opening expert reports was March 29, 2022 (ECF No. 79); opposition expert reports were due on May 27, 2022 (ECF No. 96); and the deadline for expert depositions was October 31, 2022 (ECF No. 140).

parties' disputes. ECF No. 191. On March 28, 2024, the Court issued its decision on the motions for summary judgment (ECF No. 196), and Zydus timely filed its motion for leave to supplement its expert reports by the April 18, 2024 deadline set by the Court (ECF Nos. 199, 201-02).[3]

Through the Motion, Zydus seeks permission to supplement four expert reports with events and circumstances that Zydus claims occurred after expert discovery closed:

> (1) An appellate decision in a related patent case issued in April 2023;
>
> (2) The filing of another patent case in December 2022 and summary judgment ruling in that case in March 2024;
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> (3) Updated data on the timing of Federal Circuit decisions, including the fiscal year ending September 30, 2023; and
>
> (4) The updated status of two other manufacturers' efforts to launch generic transdermal rotigotine products.

ECF No. 202-4 at 1. For reasons explained below, the Court only grants Zydus's request to supplement two expert reports with the first development listed above. The remainder of Zydus's requests are denied.

II. LEGAL STANDARD

Rule 26 of the Federal Rules of Civil Procedure governs expert disclosures. Most relevant, Rule 26(e)(1) requires a party to supplement or correct a disclosure "in a timely manner if the party learns that in some material respect the disclosure or

[3] The parties then engaged in private mediation. ECF No. 208. The Court deferred its decision on the Motion hoping that the parties would settle. They did not. On September 24, 2024, the parties confirmed at a status conference that this Motion is not moot.

response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing" or "as ordered by the court." Fed. R. Civ. P. 26(e)(1)(A). "Not every error and omission qualify for supplementation under the Federal Rules; rather, the expert reports must be incomplete or incorrect in a 'material respect.'" *Raritan Baykeeper, Inc. v. NL Indus., Inc.*, No. 09-4117, 2022 WL 815846, at *2 (D.N.J. Mar. 17, 2022) (quoting Fed. R. Civ. P. 26(e)(1)(A)). Concerned about the potential for abuse and gamesmanship, courts in this District have "repeatedly emphasized the limited scope of supplementation permitted by Rule 26(e); such supplementation is proper only for the narrow purpose of correcting inaccuracies or adding information that was not available at the time of the initial report." *Dandy v. Ethicon Women's Health & Urology*, 579 F. Supp. 3d 625, 629 (D.N.J. 2022) (quoting *Ezaki Glico Kabushiki Kaisha v. Lotte Int'l Am. Corp.*, No. 15-5477, 2019 WL 581544, at *3 (D.N.J. Feb. 13, 2019) ("*Ezaki*")). Importantly, "Rule 26(e) is not an avenue to correct failures of omission because the expert did an inadequate or incomplete preparation, add new opinions, or deepen or strengthen existing opinions." *Ezaki*, 2019 WL 581544, at *3 (quoting *In re Asbestos Prods. Liab. Litig. (No. VI)*, 289 F.R.D. 424, 425 (E.D. Pa. 2013)).

These limits are crucial to the efficient administration of justice. That is so "because a rule that allows limitless ongoing supplementation would not only erode the court's ability to control discovery but also 'invite rolling discovery in a way that would unfairly burden one party in a suit and indefinitely postpone trial.'" *Raritan*

Baykeeper, 2022 WL 815846, at *2 (quoting *Kuhns v. City of Allentown*, No. 08-2606, 2010 WL 4236873, at *3 (E.D. Pa. Oct. 26, 2010)). It is with these principles in mind that the Court must analyze Zydus's requests.

III. DISCUSSION

The Court must apply Rule 26(e) to each expert report that Zydus wishes to supplement. Before doing so, however, it is important to place the current dispute in context. Although TAPI emphasizes the age of the case and the passage of time since the close of expert discovery, TAPI cannot dispute the timeliness of the filing of Zydus's Motion, as it was clearly filed in accordance with this Court's order. *See* ECF Nos. 191, 199. Rather, TAPI's main argument is that the proposed supplemental information is not material to any of Zydus's claims or defenses. *See* ECF No. 206 at 3-9.

Each of the expert reports that Zydus seeks to supplement appear to relate to Zydus's overall legal theory—that TAPI's failure to supply the Form I rotigotine deprived Zydus of the opportunity to obtain FDA approval, launch the generic products, and reap a substantial profit. *See generally* Compl. At trial, Zydus plans to argue that the FDA would have approved its generic products and that it would have overcome any patent infringement challenges by the manufacturer of the brand products, UCB, Inc. ("UCB"). *See* ECF No. 202-4 at 2-3. As for the alleged lost profits, Zydus's analysis hinges on experts who opine as to the likely dates by which Zydus and two other manufacturers of generic drugs—Actavis Laboratories UT, Inc. ("Actavis") and Mylan Technologies Inc. ("Mylan")—would have been able enter the

market for generic transdermal rotigotine products. *Id.* at 3.

A. The Appellate Decision Issued in April 2023

Zydus seeks to supplement the expert reports issued by Audra L. Stinchcomb, Ph.D. and David L. Schwartz, J.D., to include a Federal Circuit's decision in another litigation, *UCB, Inc. v. Actavis Labs. UT, Inc.*, 65 F.4th 679 (Fed. Cir. 2023) (the "*Actavis* Litigation"). ECF No. 202-4 at 3-4. In the initial expert reports, Zydus's experts addressed UCB's litigation efforts to enforce relevant patents against Zydus and two other manufacturers of generic drugs: Actavis and Mylan. *Id.* at 3. Specifically, the expert reports state that on March 26, 2021, a district judge found that UCB's asserted claims of the patent at issue were invalid. *Id.; see UCB, Inc. v. Actavis Labs. UT, Inc.*, No. 19-474-KAJ, 2021 WL 1880993 (D. Del. Mar. 26, 2021) ("Delaware District Court"). Zydus's experts appear to rely on the Delaware District Court's decision to show that Zydus would have been able market generic transdermal rotigotine products had TAPI supplied the agreed upon Form I rotigotine. ECF No. 202-4 at 3-4. After expert discovery closed and Zydus's experts had issued their reports, the Federal Circuit affirmed the Delaware District Court's decision in the *Actavis* Litigation. *Id.* at 3. As such, Zydus moves to supplement the reports with this litigation update. *See id.* at 3-4. TAPI opposes those efforts. *See* ECF No. 206 at 5-6.

TAPI's main objection is that the initial expert reports are not incomplete or incorrect in a "material" way, as required by Rule 26(e). *Id.* at 3-9. TAPI points to the fact that the initial expert reports "already assumed that the [Delaware District

Court's] decision was correct," and therefore, any reference to the Federal Circuit's affirmance only "offer further support for previously offered opinions." *Id.* at 5-6.

The Court disagrees. It is true that the Federal Circuit's decision bolsters Zydus's initial expert reports. But just because the supplemental information bolters an already existing opinion does not automatically render it immaterial. In all other contexts, an appellate court's decision affirming or reversing a district court would be material. To make this point, assume that the Federal Circuit had reversed the Delaware District Court. There is little doubt that TAPI would have been asking the Court to compel Zydus to supplement its reports, or, alternatively, that TAPI would be seeking leave to modify its own report. Regardless, the initial reports currently state that the Delaware District Court's decision is pending appeal, a fact that is clearly incorrect. ECF No. 209 at 3. Moreover, although this Court has not interpreted either the Delaware District Court or Federal Circuit decisions, Zydus contends, and TAPI does not dispute, that the Federal Circuit affirmed the Delaware District Court for a narrower reason: it affirmed that the patent was invalid for obviousness but not for anticipation. *Id.*

The Court is convinced that Zydus is not attempting to circumvent discovery deadlines or turn an expert report into a moving target. Rather, Zydus is seeking to supplement expert reports for the purpose of correcting incomplete or incorrect material information that became available only *after* expert discovery had closed. *See Dandy*, 579 F. Supp. 3d at 629 (quoting *Ezaki*, 2019 WL 581544, at *3) ("[S]upplementation is proper only for the narrow purpose of correcting inaccuracies

or adding information that was not available at the time of the initial report."). Therefore, Dr. Stinchcomb and Professor Schwartz may update their expert reports to incorporate the *Actavis* Litigation.

B. The New Mylan Lawsuit

Next, Zydus seeks to supplement an expert report issued by Dr. Kenneth J. Miller, who opined that "a branded company such as UCB would very likely file and aggressively pursue a lawsuit" if Zydus were to reformulate its product to use Form II rotigotine as the active pharmaceutical ingredient, rather than Form I rotigotine. ECF No. 202-4 at 5. As it turned out, on December 12, 2022, UCB filed a complaint against another manufacturer of generic products, Mylan. *See UCB, Inc. v. Mylan Techs. Inc.*, No. 22-cv-00216, 2024 WL 1014144 (D. Vt. Mar. 8, 2024). Accordingly, Dr. Miller seeks to update his report to address UCB's new lawsuit against Mylan, which has now survived summary judgment.

The Court is not convinced that supplementing Dr. Miller's report complies with Rule 26(e). Zydus has not adequately explained how or why Dr. Miller's report would be incorrect or incomplete in a material way without the supplemental information. In this case, the mere fact that a lawsuit is pending is unremarkable and does not strike this Court as "material." At most, the proposed information simply bolsters Dr. Miller's opinion. Because "Rule 26(e) is not an avenue to . . . add new opinions, or deepen or strengthen existing opinions," the Court denies Zydus's request to supplement Dr. Miller's opinion. *Ezaki*, 2019 WL 581544, at *3 (quoting *In re Asbestos Prods. Liab. Litig.*, 289 F.R.D. at 425).

C. Empirical Data on the Timing of Federal Circuit Rulings

Zydus also seeks to supplement the expert report issued by Professor Schwartz, who estimated the time it would take the Federal Circuit to resolve appeals. ECF No. 202-4 at 5. On September 30, 2023, well after Professor Schwartz authored his report, the Federal Circuit updated its "Median Time to Disposition in Cases Terminated After Hearing or Submission," including its fiscal years 2022 and 2023. *Id.* Zydus seeks to supplement Professor Schwartz's report with this new empirical data. *Id.*

The Court is left to guess why this empirical data is "material," as Zydus fails to offer a meaningful explanation. Even assuming some level of materiality, this District has warned against "boundless supplementation," which could erode judicial efficiency and fairness by creating a cycle of endless updates that would indefinitely postpone trial. *Raritan Baykeeper*, 2022 WL 815846, at *3 ("Rule 26(e) is not a vehicle for recursive discovery."). Zydus shall not be permitted to continue to update its reports on a rolling basis for every year as new data is released. The Court, therefore, denies Zydus's request to update Professor Schwartz's report.

D. The Status of Actavis' and Mylan's Entry into the Market

Finally, Zydus seeks to modify the expert report issued by Dr. Laura R. Craft, MPH, who estimated Zydus's lost profits based on assumptions of when Zydus and other manufacturers, namely, Actavis and Mylan, would be able to launch their generic products. ECF No. 202-4 at 5. When Dr. Craft issued her report in March 2022, she estimated that one manufacturer would launch in January 2023 and another in July 2023. *Id.* That turned out to be incorrect, as neither manufacturer

launched on those dates. *Id.* Zydus argues that Dr. Craft's estimate is material to her analysis of when Zydus would have launched its products had TAPI supplied Form I rotigotine. *Id.* at 5-6. That estimate, in turn, allegedly impacts Dr. Craft's lost profits analysis. *Id.* at 6.

At the core, it appears that Zydus is looking to revise Dr. Craft's prediction, rather than supplement it. Again, as the Court has previously noted, in that context, "Rule 26(e) is not an avenue to correct failures of omission because the expert did an inadequate or incomplete preparation[.]" *Ezaki*, 2019 WL 581544, at *3 (quoting *In re Asbestos Prods. Liab. Litig.*, 289 F.R.D. at 425). The fact that Dr. Craft's prediction was off the mark is an insufficient basis to allow her to supplement her report. Zydus's request to supplement Dr. Craft's report is denied.

IV. CONCLUSION

For the foregoing reasons, Zydus's Motion is **GRANTED IN PART** and **DENIED IN PART**.[4] Zydus's request to supplement the expert reports issued by

[4] Zydus asks the Court consider Rule 16(b)(4) and Rule 37(c) in the event the Court rejects Zydus's arguments under Rule 26(e). Under the specific facts and procedural posture of this case, neither rule changes the Court's conclusion. Starting with Rule 16(b)(4), that Rule allows the Court to modify a scheduling order for "good cause." The Court is doubtful that Rule 16(b)(4)'s general provision applies when Rule 26(e) specifies the mechanism through which parties can supplement expert reports—which is Zydus's ultimate goal. Specifically, Rule 26(e)(2) provides that "[a]ny additions or changes" to expert reports must be "disclosed by the time the party's pretrial disclosures under Rule 26(a)(3) are due." Rule 26(a)(3)(B), in turn, requires certain pretrial disclosures to be made "at least 30 days before trial." Thus, in essence, "[t]he duty to supplement continues past the discovery deadline and up to the time of trial." *Fair Isaac Corp. v. Fed. Ins. Co.*, 337 F.R.D. 413, 419 (D. Minn. 2021) (citation omitted). And, as explained above, Rule 26(e) provides its own standard for allowing supplementation: "the expert reports must be incomplete or incorrect in a 'material respect.'" *Raritan Baykeeper*, 2022 WL 815846, at *2. If Rule 16 were to apply to this case, it would render Rule 26 superfluous, an outcome that Congress surely could not have intended. Even if the Court were to apply Rule 16(b)(4), courts in this District consider: (1) the good faith and diligence of the moving party; (2) the importance of the evidence; (3) the logistical burdens and benefits of reopening discovery; and (4) prejudice to the nonmoving party. *See Goldrich v. City of Jersey City*, No. 15-885, 2018 WL 3360764, at *1 (D.N.J. July 10, 2018) (quoting *J.G. v. C.M.*, No. 11-2887, 2014 WL 1652793, at *2 (D.N.J. Apr. 23, 2014)); *see also Kennedy v. Hoegh Autoliners Shipping PTE Ltd.*, No. 18-8599, 2021 WL 7904032, at *4-5 (D.N.J. Feb.

Audra L. Stinchcomb, Ph.D. and David L. Schwartz, J.D., to include the *Actavis* Litigation is **GRANTED**. All other requests are **DENIED**. Zydus shall serve its supplemental expert reports no later than January 17, 2025; TAPI shall serve its responsive reports no later than February 17, 2025.

HON. JOSÉ R. ALMONTE
UNITED STATES MAGISTRATE JUDGE

Dated: December 11, 2024

Orig: Clerk of the Court
cc: Counsel of Record
The Honorable Julien X. Neals, U.S.D.J.

17, 2021), *report and recommendation adopted*, 2021 WL 7841701 (D.N.J. May 24, 2021). Considering all of these factors, the result under Rule 16(b)(4) would be the same as under Rule 26(e) for the reasons articulated above and in TAPI's brief.

Similarly, the Court is unpersuaded that it is required to alter its conclusion under Rule 37(c)(1) and the factors within *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977), *overruled on other grounds by Goodman v. Lukens Steel Co.*, 777 F.2d 113 (3d Cir. 1985) ("*Pennypack*"). To begin, courts in this District have noted that a *Pennypack* analysis is *most* relevant when a court is tasked with evaluating a motion for sanctions, *i.e.*, to strike an untimely expert report, not a motion for leave to serve a supplemental expert report. *See Otsuka Pharm. Co., Ltd. v. Aurobindo Pharma Ltd.*, No. 14-3306, 2017 WL 11463663, at *4 (D.N.J. Sept. 15, 2017) (declining to apply *Pennypack* because the court was not dealing with a motion to strike an untimely expert report). Like in *Otsuka Pharm. Co.,* this Court is well within its discretion to not apply the *Pennypack* factors. Nonetheless, Zydus is correct that the Third Circuit, in *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 297-98 (3d Cir. 2012), found the *Pennypack* factors "instructive" and reversed the district court's denial of Plaintiffs' request to submit alternate damages calculations within a modified expert report. In *ZF Meritor*, the Third Circuit found "the most important [*Pennypack*] factor in th[e] case [to be] the critical nature of the evidence, and the consequences if permission to amend is denied." *Id.* at 299. This was particularly so because "[e]xpert testimony is necessary to establish damages in an antitrust case," and therefore, "without additional damages calculations, it [was] clear that Plaintiffs [would] be unable to pursue damages[.]" *Id.* As explained in detail above, the Court does not find the additional events and information proffered in three of Zydus's requests to be "material" or "critical evidence." In other words, unlike in *ZF Meritor*, here Zydus is not being subjected to the "extreme sanction" of being barred from pursuing damages, but rather it is being barred from correcting predictions or bolstering certain of its expert reports with information that Zydus failed to show is material. As such, the Court declines to apply Rule 37(c)(1) and the remaining *Pennypack* factors.